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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,419	01/23/2004	Robert Turtott	VT0282-US4	8194
24473	7590	07/24/2006	EXAMINER	
STEVEN M MITCHELL PACESETTER INC 701 EAST EVELYN AVENUE SUNNYVALE, CA 94086			LAYNO, CARL HERNANDZ	
		ART UNIT	PAPER NUMBER	
		3766		

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/764,419	TURCOTT, ROBERT
	<b>Examiner</b> Carl H. Layno	<b>Art Unit</b> 3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 January 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 21-44 is/are allowed.
- 6) Claim(s) 1,14,15 and 18 is/are rejected.
- 7) Claim(s) 2-13,16,17,19 and 20 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 January 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/23/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for priority filing as a Continuation-In-Part (CIP) of U.S Application Serial No. 10/208,081, filed on July 29, 2002, now U.S Patent No. 6,942,622, which is a Continuation-In-Part (CIP) of U.S Application Serial No. 09/467,298, filed on December 17,1999, now U.S Patent No. 6,480,733, which is a Continuation-In-Part (CIP) of U.S Application Serial No. 09/438,017, filed on November 10, 1999, now U.S Patent No. 6,409,675.

### ***Information Disclosure Statement***

2. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449), which was received by the Office on January 23, 2004.

### ***Drawings***

3. The drawings are objected to because of the minor informalities found by the Draftsperson. See the attached PTO-948. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where

necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

*Specification*

4. The disclosure is objected to because of the following informalities: -p.1, paragraph [0001], the status of U.S Application Serial No. 10/208,081 should be updated to reflect the fact that this application is now U.S Patent No. 6,942,622.

Appropriate correction is required.

*Claim Objections*

5. Claim 20 is objected to under 37 CFR 1.75(b) since it fails to "differ substantially" from claim 19. Specifically, the language of claim 20 is a duplicate of claim 19.

*Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1, 14, 15, and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cowings (US 5,694,939).

The Cowings (US 5,694,939) patent describes a autogenic feedback training /exercise (AFTE) method and apparatus that uses finger mounted photoplethysmography sensors rings 57 (Fig.2 – col.7, lines 45-52) to sense the volume of blood flow for each cardiac pulse. Among other parameters sensed by the plethysmograph is impedance related to blood pressure (col.8, lines 22-28). It would be obvious, if not inherent, for the device to be capable of measuring pulse rate, which is the frequency of the detected cardiac pulses since this capability is manifest in the operation of the wrist display unit 30 (col.9, lines 39-49). The device of Cowings monitors and displays many parameters including “Vagal Tone” (col.20, line 23), which the Examiner considers to be a subset of autonomic tone, and pulse rate (“PULSE RT”). Since vagal tone is a

function of the sensed heart rate (col.20, lines 37-38), the vagal tone would also be a function of the pulse rate.

8. Claims 1, 14, 15, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Barnea (US 6,162,188).

The Barnea (US 6,162,188) patent describes a penile tumescence monitoring device (Fig.1), whose method of operation reads upon applicant's claimed method steps. Specifically, Barnea mentions that penile tumescence is a function of autonomic neural tone (col.1, lines 61-62), which when normally active, causes penile erections. The Barnea device utilizes photoplethysmograph sensor 40 (Fig.6 – col.9, lines 17-39) in a ring cuff surrounding a patient's penis 10. Changes in the amount of blood in the penis are monitored and data analyzed by an attached computer processor. An index of tumescence is generated. The Examiner considers this parameter to be a proxy for autonomic tone.

*Allowable Subject Matter*

9. Claims 2-13, 16, 17, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 21-44 are allowed.

11. The following is a statement of reasons for the indication of allowable subject matter:

As written, independent claims 21, 36, and 39 recite the capability of performing a pacing interval optimization in combination with photoplethysmography signal detection. None of the prior art reference(s) found by the Examiner appear to teach this combination. In addition, claims 21 and 36 recite the capability of monitoring a patient's autonomic tone. Consequently, the Examiner deems these claims and their depending claims to be allowable.

***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Carl H. Layno

CARL LAYNO  
PRIMARY EXAMINER

CHL  
7/19/2006